

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

IN RE: DIET DRUGS (PHENTERMINE/ FENFLURAMINE/DEXFENFLURAMINE) PRODUCTS LIABILITY LITIGATION)	
)	MDL NO. 1203
)	
THIS DOCUMENT RELATES TO:)	
)	
SHEILA BROWN, et al.)	
)	CIVIL ACTION NO. 99-20593
v.)	
)	
AMERICAN HOME PRODUCTS CORPORATION)	2:16 MD 1203

MEMORANDUM IN SUPPORT OF SEPARATE PRETRIAL ORDER NO. 9174

Bartle, J.

December 5, 2013

Mary S. Webb ("Ms. Webb" or "claimant"), a class member under the Diet Drug Nationwide Class Action Settlement Agreement ("Settlement Agreement") with Wyeth,¹ seeks benefits from the AHP Settlement Trust ("Trust"). Based on the record developed in the show cause process, we must determine whether claimant has demonstrated a reasonable medical basis to support her claim for Matrix Compensation Benefits ("Matrix Benefits").²

1. Prior to March 11, 2002, Wyeth was known as American Home Products Corporation. In 2009, Pfizer, Inc. acquired Wyeth.

2. Matrix Benefits are paid according to two benefit matrices (Matrix "A" and Matrix "B"), which generally classify claimants for compensation purposes based upon the severity of their medical conditions, their ages when they are diagnosed, and the presence of other medical conditions that also may have caused or contributed to a claimant's valvular heart disease ("VHD"). See Settlement Agreement §§ IV.B.2.b. & IV.B.2.d.(1)-(2). Matrix A-1 describes the compensation available to Diet Drug Recipients with
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To seek Matrix Benefits, a claimant must first submit a completed Green Form to the Trust. The Green Form consists of three parts. The claimant or the claimant's representative completes Part I of the Green Form. Part II is completed by the claimant's attesting physician, who must answer a series of questions concerning the claimant's medical condition that correlate to the Matrix criteria set forth in the Settlement Agreement. Finally, claimant's attorney must complete Part III if claimant is represented.

Under the Settlement Agreement, only eligible claimants are entitled to Matrix Benefits. Generally, a claimant is considered eligible for Matrix Benefits if he or she is diagnosed with mild or greater aortic and/or mitral regurgitation by an echocardiogram performed between the commencement of Diet Drug use and the end of the Screening Period.³ See Settlement Agreement §§ IV.B.1.a. & I.22.

In May, 2010, claimant submitted a completed Green Form to the Trust signed by her attesting physician, Stephen

2. (...continued)
serious VHD who took the drugs for 61 days or longer and who did not have any of the alternative causes of VHD that made the B matrices applicable. In contrast, Matrix B-1 outlines the compensation available to Diet Drug Recipients with serious VHD who were registered as having only mild mitral regurgitation by the close of the Screening Period or who took the drugs for 60 days or less or who had factors that would make it difficult for them to prove that their VHD was caused solely by the use of these Diet Drugs.

3. See Settlement Agreement § IV.A.1.a. (Screening Program established under the Settlement Agreement).

Raskin, M.D. Based on an echocardiogram dated November 23, 2009,⁴ Dr. Raskin attested in Part II of claimant's Green Form that Ms. Webb suffered from mild mitral regurgitation and had surgery to repair or replace the aortic and/or mitral valve(s) following the use of Pondimin[®] and/or Redux[™].⁵ Based on such findings, claimant would be entitled to Matrix B-1,⁶ Level III benefits in the amount of \$134,221.⁷

In the report of claimant's May 5, 2003 echocardiogram, the reviewing cardiologist, Tin M. Way, M.D., F.A.C.C., stated

4. Because claimant's November 23, 2009 echocardiogram was performed after the end of the Screening Period, claimant relied on an echocardiogram dated May 5, 2003 to establish her eligibility to receive Matrix Benefits.

5. Dr. Raskin also attested that claimant suffered from mild aortic regurgitation, aortic root dilation > 5.0 cm, a reduced ejection fraction in the range of 50% to 60%, and New York Heart Association Functional Class II symptoms. These conditions are not at issue in this claim.

6. The Settlement Agreement requires the payment of reduced Matrix Benefits for a claim based on damage to the mitral valve if the Diet Drug Recipient was diagnosed with mild mitral regurgitation by an echocardiogram performed between the commencement of Diet Drug use and the end of the Screening Period. See Settlement Agreement § IV.B.2.d.(2)(a). Although claimant requested Matrix A-1 benefits, she did not contest the Trust's determination that the her claim is payable, if at all, on Matrix B-1.

7. Under the Settlement Agreement, a claimant is entitled to Level III benefits if he or she suffers from "left sided valvular heart disease requiring ... [s]urgery to repair or replace the aortic and/or mitral valve(s) following the use of Pondimin[®] and/or Redux[™]." Settlement Agreement § IV.B.2.c.(3)(a). As the Trust concedes that Ms. Webb underwent surgery to repair her mitral valve, the only issue is whether she is eligible for benefits.

that claimant had "trivial to mild mitral regurgitation."⁸ Dr. Way, however, did not specify a percentage as to claimant's level of mitral regurgitation. Under the definition set forth in the Settlement Agreement, mild mitral regurgitation is defined as "(1) either the RJA/LAA ratio is more than five percent (5%) or the mitral regurgitant jet height is greater than 1 cm from the valve orifice, and (2) the RJA/LAA ratio is less than twenty percent (20%)." Settlement Agreement § I.38.

In August, 2010, the Trust forwarded the claim for review by Alan J. Bier, M.D., F.A.C.P., F.A.C.C., F.A.S.E., one of its auditing cardiologists. In audit, Dr. Bier determined that there was no reasonable medical basis for finding that Ms. Webb had at least mild mitral regurgitation based on her May 5, 2003 echocardiogram. Specifically, Dr. Bier explained, "There is only a trace of mitral regurgitation in early systole. It lasts only 1-2 frames and is consistent with normal backflow, not significant mitral regurgitation."

Based on Dr. Bier's finding, the Trust issued a post-audit determination denying Ms. Webb's claim. Pursuant to the Rules for the Audit of Matrix Compensation Claims ("Audit Rules"), claimant contested this adverse determination.⁹ In

8. As noted in the Report of Auditing Cardiologist Opinions Concerning Green Form Questions at Issue, trace, trivial, or physiologic regurgitation is defined as a "[n]on-sustained jet immediately (within 1 cm) behind the annular plane or <+ 5% RJA/LAA."

9. Claims placed into audit on or before December 1, 2002 are
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contest, Ms. Webb argued that her May 5, 2003 echocardiogram and Dr. Way's Gray Form representation of mild mitral regurgitation establish a reasonable medical basis for finding mild mitral regurgitation.¹⁰ In addition, claimant contended that she relied on Dr. Way's representation of mild mitral regurgitation and, because her echocardiogram was conducted as part of the Screening Program, the Trust is estopped from denying that she had mild mitral regurgitation.

The Trust then issued a final post-audit determination, again denying Ms. Webb's claim. Claimant disputed this final determination and requested that the claim proceed to the show cause process established in the Settlement Agreement. See Settlement Agreement § VI.E.7.; PTO No. 2807, Audit Rule 18(c). The Trust then applied to the court for issuance of an Order to show cause why her claim should be paid. On August 16, 2011, we issued an Order to show cause and referred the matter to the Special Master for further proceedings. See PTO No. 8666 (Aug. 16, 2011).

9. (...continued)
governed by the Policies and Procedures for Audit and Disposition of Matrix Compensation Claims in Audit, as approved in Pretrial Order ("PTO") No. 2457 (May 31, 2002). Claims placed into audit after December 1, 2002 are governed by the Audit Rules, as approved in PTO No. 2807 (Mar. 26, 2003). There is no dispute that the Audit Rules contained in PTO No. 2807 apply to Ms. Webb's claim.

10. Under the Settlement Agreement, the Gray Form was used to report on the results of echocardiograms performed in the Screening Program. See Settlement Agreement §§ VI.C.2.f., VI.C.4.a.(8)

Once the matter was referred to the Special Master, the Trust submitted its statement of the case and supporting documentation. Claimant then served a response upon the Special Master reasserting the same arguments she made at contest. The Trust informed the Special Master by letter dated December 21, 2011 that it did not intend to submit a reply. Under the Audit Rules, it is within the Special Master's discretion to appoint a Technical Advisor¹¹ to review claims after the Trust and claimant have had the opportunity to develop the Show Cause Record. See Audit Rule 30. The Special Master assigned a Technical Advisor, Sandra V. Abramson, M.D., F.A.C.C., to review the documents submitted by the Trust and claimant and to prepare a report for the court. The Show Cause Record and Technical Advisor Report are now before the court for final determination. See id. Rule 35.

The issue presented for resolution of this claim is whether claimant has met her burden of proving that there is a reasonable medical basis for finding that Ms. Webb suffered from at least mild mitral regurgitation between the commencement of Diet Drug use and the end of the Screening Period. See id. Rule 24. Ultimately, if we determine that there is no reasonable

11. A "[Technical] [A]dvisor's role is to act as a sounding board for the judge--helping the jurist to educate himself in the jargon and theory disclosed by the testimony and to think through the critical technical problems." Reilly v. United States, 863 F.2d 149, 158 (1st Cir. 1988). In a case such as this, where conflicting expert opinions exist, it is within the discretion of the court to appoint a Technical Advisor to aid it in resolving technical issues. Id.

medical basis for the claim, we must affirm the Trust's final determination and may grant such other relief as deemed appropriate. See id. Rule 38(a). If, on the other hand, we determine that there is a reasonable medical basis for the claim, we must enter an Order directing the Trust to pay the claim in accordance with the Settlement Agreement. See id. Rule 38(b).

The Technical Advisor, Dr. Abramson, reviewed claimant's echocardiogram and concluded that there was no reasonable medical basis for finding mild mitral regurgitation on claimant's May 5, 2003 echocardiogram. Specifically, Dr. Abramson explained, in pertinent part:

I reviewed the transthoracic echocardiogram from 5/5/03. The Eligibility Echocardiogram from 5/5/03 showed no mitral regurgitation on the parasternal views and none to, at most, trace mitral regurgitation on the apical views. Most of the cardiac cycles showed no mitral regurgitation. The continuous wave Doppler of this mitral regurgitant jet is very faint, which is consistent with trace mitral regurgitation.

After reviewing the entire Show Cause Record, we find the claimant's arguments are without merit. As an initial matter, claimant does not adequately rebut the findings of the auditing cardiologist or the Technical Advisor. Dr. Bier reviewed claimant's May 5, 2003 echocardiogram and determined that "[t]here is only a trace of mitral regurgitation in early systole. It lasts only 1-2 frames and is consistent with normal backflow, not significant mitral regurgitation." Similarly, Dr. Abramson reviewed claimant's May 5, 2003 echocardiogram and

concluded that it was diagnostic of, "at most, trace mitral regurgitation." Although claimant contested Dr. Bier's findings, she did not identify any error in Dr. Bier's analysis. Instead, she argued only that the Trust should be estopped from denying that Ms. Webb had mild mitral regurgitation based on Dr. Way's Gray Form representation. Moreover, despite an opportunity to do so, claimant did not submit a response to the Technical Advisor Report. See Audit Rule 34. Mere disagreement with the auditing cardiologist and the Technical Advisor without identifying any specific errors by them is insufficient to meet a claimant's burden of proof.

We also reject claimant's assertion that she is entitled to Matrix Benefits because her eligibility echocardiogram was conducted in the Screening Program for Fund A Benefits under the Settlement Agreement. See Settlement Agreement § IV.A. The Settlement Agreement clearly provides that the sole benefit a class member is entitled to receive for a favorable echocardiogram under the Screening Program is a limited amount of medical services or a limited cash payment:

All Diet Drug Recipients in Subclass 2(b) and those Diet Drug Recipients in Subclass 1(b) who have been diagnosed by a Qualified Physician as FDA Positive by an Echocardiogram performed between the commencement of Diet Drug use and the end of the Screening Period, will be entitled to receive, at the Class Member's election, either (i) valve-related medical services up to \$10,000 in value to be provided by the Trust; or (ii) \$6,000 in cash.

Id. § IV.A.1.c. Thus, by the plain terms of the Settlement Agreement, a Screening Program echocardiogram does not automatically entitle a claimant to Matrix Benefits.

Indeed, this conclusion is confirmed by the Settlement Agreement provisions concerning claimants eligible for Matrix Benefits. Specifically, claimants receiving a diagnosis of FDA Positive or mild mitral regurgitation merely become eligible to seek Matrix Benefits. See id. § IV.B.1. Further, adopting claimant's position would be inconsistent with § VI.E. of the Settlement Agreement, which governs the audit of claims for Matrix Benefits, as well as this Court's decision in PTO No. 2662, which mandated a 100% audit requirement for all claims for Matrix Benefits. See Mem. in Supp. of PTO No. 2662, at 13 (Nov. 26, 2002). As nothing in the Settlement Agreement supports the conclusion that a favorable Screening Program echocardiogram for purposes of Fund A Benefits results in an immediate entitlement to Matrix Benefits, we decline claimant's request to interpret the Settlement Agreement in this fashion.

For the foregoing reasons, we conclude that claimant has not met her burden of proving that there is a reasonable medical basis for finding that Ms. Webb had at least mild mitral regurgitation between the commencement of Diet Drug use and the end of the Screening Period. Therefore, we will affirm the Trust's denial of Ms. Webb's claim for Matrix B-1, Level III benefits.